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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,606	12/22/1999	HEINZ PETER VOLLMERS	PATWA-2	5150

21559 7590 11/18/2004

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/469,606	VOLLMERS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,42, 43 and 45-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) *1,4,42,43 and 45-50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 30, 2004 has been entered.

2. Claims 1, 4, 42, 43 and 45-50 are pending.

Claims 45-50 have been added.

Claim 1 has been amended.

Claim 44 has been cancelled.

Claims 1, 4, 42, 43 and 45-50 are examined on the merits.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 50 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have added new claim 52 which includes the recitation "...said section is a section of a glycoprotein that has an apparent molecular weight of about 82kD...". Applicants assert that support for the newly added claim can be found in original claim 1 and at page 5, lines 7-23, see Applicants' remarks submitted August 30, 2004, page 5. The Examiner has reviewed the original claim and the specification at the designated page. The original claim does not reference any molecular weight and the specification notes that the glycoprotein has an apparent molecular weight of about 82kD. New claim 50 suggests that a section of the glycoprotein has the molecular weight of about 82kD and not the glycoprotein in its entirety has a molecular weight of about 82kD. The specification and new claim 50 are not consistent in regard to the molecular weight. Applicants should delete the new matter or pointedly express where in the specification support can be found for a section of the glycoprotein having the molecular weight of about 82kD.

5. The rejection of claims 1, 4, 42, 43 and newly added claims 45-50 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and made. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 44 has been cancelled.

In anticipation of the instant rejection Applicants recite several points from the MPEP, specifically section 2163.02 (Eighth Edition, Revision 2, May 2004) in an attempt to establish that their specification clearly meets the standard for adequate written description and assert that "[their] specification allows one skilled in the art to recognize that one has invented what is claimed." Applicants also aver that "...[their] claims are not directed to a particular section of the CD55 protein, and, therefore, Applicants submit that the basis of the rejection does not apply to claim 1 and its dependent claims." The Examiner has reviewed the specification in its entirety, carefully reviewed and considered Applicants' Remarks and has found them unpersuasive.

The specification continues to be remiss of information detailing what defines tumor-specific N-linked glycostructure and how one of ordinary skill in the art could identify the said structure. There is insufficient guidance regarding the section of the protein that is to have this specific structure. Applicants themselves reiterate an obscurity with the claims, "[t]hese claims are not directed to a particular section of the CD55 protein", see page 8 of Remarks. Essentially, the claims do not define or characterize the glycostructure. Not knowing or not being able to clearly define the tumor specific N-linked glycostructure, which is germane to the claimed invention, implies that Applicants have not adequately described the species and consequently are not in possession of the genus. In view of Applicants not being able to define, nor characterize the glycostructure one of ordinary skill in the art is not clear on the variability that possibly exists within the genus of glycoproteins. The Official Gazzette makes plain "...when there is substantial variation within a genus, one must describe a

sufficient variety of species to reflect the variation within the genus.", see 1422 Official Gazette 174, January 30, 2001. The specification submits that the claimed invention reads on "...variants with deletions, insertions and/or substitutions in the amino acid primary structure...", see page 5, lines 18-23. It is not clear how one of ordinary skill in the art could definitively recognize whether or not they were also in possession of Applicants' claimed invention, thereby infringing on Applicants' claimed invention. Applicants' claims continue to read on a genus. There is a plethora of species that could be encompassed by the broad claims. Applicants are not entitled to all proteins capable of exhibiting this structure or containing the amino acid primary structure of CD55. "For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." See the Official Gazette, 1272 OG 174, January 30, 2001.

In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court

states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 50 is vague and indefinite in the recitation "...section is a section of a glycoprotein that has an apparent molecular weight of about 82 kD...". It is not clear if the section of the glycoprotein has the 82kD weight or that the glycoprotein itself ahs the weight of 82 kD. Applicants are requested to clarify the claim language.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 43 and 45-50 rejected under 35 U.S.C. 102(b) as being anticipated by Karnauchow et al. (Journal of Virology 70(8): 5143-5152, August 1996). Karnauchow discloses a HeLa cell glycoprotein of approximately 75kDa, see abstract. It is within the purview of the Examiner that this disclosed molecular weight is about 82kD. Claim 50 has been identified as being indefinite. The Examiner is interpreting claim 50 to read on a glycoprotein with the molecular weight of about 82kD, hence the prior art reads on this claim as well. Monoclonal antibody (Mab), EVR1 identified the tumor cell glycoprotein, see abstract. The disclosed protein appears to be the same as Applicants thereby inherently possessing a tumor-specific N-linked glycostructure and present on the specified cell line. The disclosed antibody is specific for the glycostructure and consequently is capable of presenting the results listed in claims 43 and 45-49. Since the Patent and Trademark Office does not have the facilities for examining and comparing the glycoprotein and the antibody of the Applicants' with the protein and antibody of the prior art, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the glycoprotein and antibody in the claimed invention to be used in the prior art. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

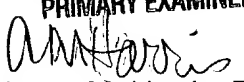
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(571)272-0831. The examiner works a flexible schedule, but can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
08 November 2004